DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 13 2007

Re: Kepivance
Docket No.: 2005E-0245

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,677,278, filed by Chiron Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Kepivance (palifermin), the human biological product claimed by the patent.

The total length of the regulatory review period for Kepivance (palifermin) is 3,303 days. Of this time, 3,119 days occurred during the testing phase and 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 2, 1995.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 2, 1995.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: June 15, 2004.

   The applicant claims May 14, 2004, as the date the biologics license application (BLA) for Kepivance (BLA 125103) was initially submitted. However, FDA records indicate that the final reviewable unit of BLA 125103 was received by FDA on June 15, 2004.

3. The date the application was approved: December 15, 2004.

   FDA has verified the applicant's claim that BLA 125103 was approved on December 15, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: David R. Marsh
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